

CLAIMS

The invention claimed is:

1. A method of enhancing an immunogenic response in a mammalian subject, the method comprising administering a biodegradable polymeric delivery system comprising a biologically effective amount of one or more antigens and one or more basic additives to the mammalian subject.
2. The method of claim 1 wherein the antigen is selected from the group consisting of nucleic acids, proteins, polypeptides, peptides, polysaccharides, hapten conjugates, and combinations thereof.
3. The method of claim 2 wherein the antigen is a peptide.
4. The method of claim 1 wherein the basic additive is characterized by having a pH of a saturated solution at 37°C in the range from about 6.8 to about 12.5 and a solubility in water at 37°C from 1.2×10^{-2} to about 3×10^{-11} .
5. The method of claim 1 wherein the basic additive is selected from the group consisting of magnesium carbonate, magnesium hydroxide, magnesium oxide, magnesium trisilicate, zinc carbonate, zinc hydroxide, zinc phosphate, aluminum hydroxide, basic aluminum carbonate, dihydroxyaluminum sodium carbonate, dihydroxyaluminum aminoacetate, ammonium phosphate, calcium phosphate, calcium hydroxide, magaldrate, calcium sulfate and combinations thereof.
6. The method of claim 1 wherein the mammalian subject is a human.
7. A method of enhancing an immunogenic response to human chorionic gonadatropin (hCG) in a subject, the method comprising administering a biodegradable polymeric delivery system comprising a biologically effective amount of an hCG antigen and a basic additive to the subject.
8. The method of claim 7 wherein the hCG antigen is a carboxyl terminal peptide (CTP) of the beta subunit of hCG.

9. The method of claim 7 wherein polymeric delivery system comprises from 0.08 to 20% antigen based on the weight of the polymer.
10. The method of claim 7 wherein the antigen is conjugated to the polymeric delivery system and encapsulated in the polymeric delivery system.
11. The method of claim 7 wherein the antigen is conjugated to the polymeric delivery system.
12. The method of claim 7 wherein the antigen is encapsulated in the polymeric delivery system.
13. The method of claim 7 wherein the basic additive is characterized by having a pH of a saturated solution at 37°C in the range from about 6.8 to about 12.5 and a solubility in water at 37°C from 1.2×10^{-2} to about 3×10^{-11} .
14. The method of claim 7 wherein the basic additive is selected from the group consisting of magnesium carbonate, magnesium hydroxide, magnesium oxide, magnesium trisilicate, zinc carbonate, zinc hydroxide, zinc phosphate, aluminum hydroxide, basic aluminum carbonate, dihydroxyaluminum sodium carbonate, dihydroxyaluminum aminoacetate, ammonium phosphate, calcium phosphate, calcium hydroxide, magaldrate, calcium sulfate and combinations thereof.
15. The method of claim 14 wherein the basic additive is MgCO_3 .
16. The method of claim 7 wherein the ratio of basic additive to antigen is from 0.5:1 to 30:1 (w/w).
17. The method of claim 16 wherein the ratio of basic additive to antigen is about 4:1 (w/w).
18. The method of claim 7 wherein the ratio of basic additive to biodegradable polymer is from 0.5 to 20% (w/w).
19. The method of claim 18 wherein the ratio of basic additive to biodegradable polymer is from 1 to 7% (w/w).

20. The method of claim 7 wherein basic additive is added at a level of 3% or less based on the weight of the polymer.
21. The method of claim 7 wherein the biodegradable polymeric delivery system is a poly(lactide-co-glycolide) (PLGA) delivery system.
22. The method of claim 21 wherein the PLGA is poly(D-L-lactide-co-glycolide).
23. The method of claim 21 wherein the ratio of lactide/lactic acid to the ratio of glycolide/glycolic acid is in the range from 100:0 to 0:100.
24. The method of claim 23 wherein the ratio of lactide/lactic acid to the ratio of glycolide/glycolic acid is in the range from 100:0 to 50:50.
25. The method of claim 7 wherein the PLGA polymeric delivery system further comprises an adjuvant.
26. The method of claim 7 wherein the PLGA delivery system further comprises an excipient.
27. An immunogenic composition for eliciting an immune response against an antigen comprising:
- a) a biodegradable polymeric delivery system;
 - b) a biologically effective amount of an antigen; and
 - a) a basic additive.
28. An immunogenic composition for eliciting an immune response against human chorionic gonadatropin (hCG) comprising:
- a) a poly(lactide-co-glycolide) polymeric delivery system; wherein the ratio of lactide/lactic acid to the ratio of glycolide/glycolic acid is in the range from 100:0 to 50:50;

b) 0.08 to 20% (w/w) of an hCG antigen, based on the weight of the polymer, wherein the hCG antigen is a carboxyl terminal peptide (CTP) of the beta subunit of hCG; and

c) 0.5 to 20% (w/w) of a basic additive, based on the weight of the polymer, wherein the basic additive is selected from the group consisting of magnesium carbonate, magnesium hydroxide, magnesium oxide, magnesium trisilicate, zinc carbonate, zinc hydroxide, zinc phosphate, aluminum hydroxide, basic aluminum carbonate, dihydroxyaluminum sodium carbonate, dihydroxyaluminum aminoacetate, ammonium phosphate, calcium phosphate, calcium hydroxide, magaldrate, calcium sulfate and combinations thereof.

29. The immunogenic composition of claim 28 wherein the ratio of basic additive to antigen is about 4:1.